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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/030,571	02/24/1998	CHARLES R. CANTOR	25491-2401G	7542

24961 7590 01/21/2003

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EXAMINER	
FORMAN, BETTY J	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 01/21/2003

4

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/030,571	CANTOR ET AL.	
	Examiner	Art Unit	
	BJ Forman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 November 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *70,72-79,92-94 and 123-126* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *70,72-79,92-94 and 123-126* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *36* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

FINAL ACTION

1. This action is in response to papers filed 7 October 2002 in Paper No. 35 in which claims 70, 74 and 92-94 were amended, claims 71, 89-91 and 114-116 were canceled and claims 117-120 were added. New claims 117-120 have been renumbered as claims 123-126 according to 37 C.F.R. 1.126. All of the amendments have been thoroughly reviewed and entered. The previous rejections in the Office Action of Paper No. 32 dated 5 June 2002 are withdrawn in view of the amendments. All of the arguments have been thoroughly reviewed but are deemed moot in view of the amendments, withdrawn rejections and new grounds for rejections. The arguments are discussed below as they apply to the new rejections. New grounds for rejection are discussed.

Claims 70, 72-79, 92-94 and 123-126 are under prosecution.

Nucleic Acid Sequence Rules

2. The paper copy and computer readable copy of the nucleic acid sequence listing filed 19 November 2002 in Paper No. 39 is acknowledged.

Double Patenting Rejection

3. The Terminal Disclaimer filed 7 October 2002 in Paper No. 37 is acknowledged. The double patenting rejection over U.S. Patent No. 6,248,767 is withdrawn in view of the Terminal Disclaimer.

Information Disclosure Statement

4. The references listed on the 1449 filed 27 September 2002 in Paper No. 36have been reviewed and considered.

Specification

5. The amendment filed 7 October 2002 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The amendment adds new claim 126 (incorrectly numbered, claim 120). Claim 126 recites "wherein the single-stranded portion in 50% or more of the probes of the array is replaced with a nucleotide sequence of length R+L, representing those nucleotide sequences of length R+L present in the target nucleic acid sample, by extending the single-stranded portion of the probes by ligation of a 3'-blocked nucleotide of length L using hybridized target at template, whereby the random nucleotide sequence of length R is extended." On page 3 of Applicant's response, Applicant states that new claims 123-125 (117-119) find basis on pages 12, 13 and 24. The cited passages provide support for new claims 123-125 (117-119) but the passages do not provide support for new claim 126 (120). While the specification as filed provides support for the array of probes recited in Claim 74 having a random sequence length R (e.g. page 6, lines 3-9) the specification does not provide support for the newly claimed "the single-stranded portion in 50% or more of the probes of the array is replaced with a nucleotide sequence of length R+L"; or "ligation of a 3'-blocked nucleotide of length L". Therefore the amendments introduce new matter into the disclosure of the specification.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

35 U.S.C. 112: first paragraph

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claim 126 (120) is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The recitation "wherein the single-stranded portion in 50% or more of the probes of the array is replaced with a nucleotide sequence of length R+L, representing those nucleotide sequences of length R+L present in the target nucleic acid sample, by extending the single-stranded portion of the probes by ligation of a 3'-blocked nucleotide of length L" is recited in new claim 126. However, the specification fails to define or provide any disclosure to support such claim recitation.

On page 3 of Applicant's response, Applicant states that new claims 123-125 (117-119) find basis on pages 12, 13 and 24. The cited passages provide support for new claims 123-125 (117-119) but the passages do not provide support for new claim 126 (120). While the specification as filed provides support for the array of probes recited in Claim 74 having a random sequence length R (e.g. page 6, lines 3-9) the specification does not provide support for the newly claimed "the single-stranded portion in 50% or more of the probes of the array is replaced with a nucleotide sequence of length R+L"; or "ligation of a 3'-blocked nucleotide of length L".

Therefore, the specification fails to define or provide any disclosure to support the limitations of new claim 126.

MPEP 2163.06 notes "IF NEW MATTER IS ADDED TO THE CLAIMS, THE EXAMINER SHOULD REJECT THE CLAIMS UNDER 35 U.S.C. 112, FIRST PARAGRAPH - WRITTEN DESCRIPTION REQUIREMENT. *IN RE RASMUSSEN*, 650 F.2D 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application." MPEP 2163.06 further notes "WHEN AN AMENDMENT IS FILED IN REPLY TO AN OBJECTION OR REJECTION BASED ON 35 U.S.C. 112, FIRST PARAGRAPH, A STUDY OF THE ENTIRE APPLICATION IS OFTEN NECESSARY TO DETERMINE WHETHER OR NOT "NEW MATTER" IS INVOLVED. *APPLICANT SHOULD THEREFORE SPECIFICALLY POINT OUT THE SUPPORT FOR ANY AMENDMENTS MADE TO THE DISCLOSURE*" (emphasis added).

35 U.S.C. 112: second paragraph

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claim 126 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 126 is indefinite in lines 4-5 for the recitation "the target nucleic acid sample" because the recitation lacks proper antecedent basis in claim 74. It is suggested that Claim 126 be amended to provide proper antecedent basis e.g. replace "the" with "a".

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claims 70, 72, 73 and 125 are rejected under 35 U.S.C. 102(e) as being anticipated by Deugau et al (U.S. Patent No. 5,508,169, filed 6 April 1990).

Regarding Claim 70, Deugau et al disclose an array of 4^r nucleic acid probes (i.e. complete panel of indexing linkers) wherein each probe has a double-stranded portion at the 3' terminus, a single stranded portion at the 5' terminus and a random nucleotide sequence of length R within the single-stranded portion (Column 11, lines 14-25, Fig. 2 and Claim 33). Figure 2 clearly illustrates the embodiment of Deugau probe comprising a double-stranded portion at the 3' terminus and a single stranded portion at the 5' terminus. As such, Deugau et al clearly disclose the nucleic acid probes of Claim 70.

Regarding Claim 72, Deugau et al disclose the array wherein the double-stranded portion (i.e. common sequence # 1026, # 1504 and # 1701) is between about 3-20 nucleotide and the single stranded portion is between about 3-20 nucleotides (Columns 15-16, Table I and Table II).

Regarding Claim 73, Deugau et al disclose the array wherein the double-stranded portion (i.e. common sequence # 1026, # 1504 and # 1701) is between 3-20 nucleotide and the single stranded portion is between 3-20 nucleotides (Columns 15-16, Table I and Table II).

Regarding Claim 125, Deugau et al disclose an array comprising up to $4(2^r-1)$ nucleic acid probes wherein each probe comprises a random nucleotide sequence of length R (Column 9, lines 29-42 and Claim 25). Deugau et al disclose the array comprises at least two probes (Column 9, lines 29-31) and they claim the array comprises at least eight different probes (Claim 25 (ii)). As such, Deugau et al disclose the array comprising "up to $4(2^r-1)$ nucleic acid probes" as claimed.

Response to Arguments

12. Applicant states that Deugau et al discloses a comprehensive panel of indexing linker containing all possible unique cohesive ends wherein the minimum number of probe required for a comprehensive panel is $[N \times (N + 1)]/2$. Applicant argues that Deugau et al does not disclose an array of probes which contains a double-stranded portion at the 3' terminus and a single-stranded portion at the 5' terminus or a double-stranded portion at one terminus and a single-stranded portion at the opposite terminus. The argument has been considered but is not found persuasive because Deugau et al clearly illustrates the claimed probes which contains a double-stranded portion at the 3' terminus and a single-stranded portion at the 5' terminus and a double-stranded portion at one terminus and a single-stranded portion at the opposite terminus (Fig. 2 and (Column 11, lines 14-25).

Applicant argues that Deugau et al does not disclose an array when one strand of the double-stranded portion is conjugated to a coupling agent through which the probes are fixed to a solid support. The argument has been considered but is deemed moot in view of the fact that the argument addresses Claim 74 as amended and in view of the fact that the previous rejection of Claim 74 under 35 U.S.C. 102 is withdrawn.

Applicant argues that Deugau et al does not disclose an array of 4^r nucleic acid probes or a probe array of $4(2^r-1)$ probes. The argument has been considered but is not found persuasive because Deugau et al clearly discloses an array of 4^r nucleic acid probes (Column

11,lines 14-25 and Claim 33). It is noted that new claim 125 is drawn to an array comprising **up to** $4(2^r-1)$ nucleic acid probes. As stated above, Deugau et al clearly discloses an array comprising **up to** $4(2^r-1)$ nucleic acid probes (Column 9, lines 29-42 and Claim 25). Deugau et al disclose the array comprises at least two probes (Column 9, lines 29-31) and they claim the array comprises at least eight different probes (Claim 25 (ii)). As such, Deugau et al disclose the array comprising "up to $4(2^r-1)$ nucleic acid probes" as claimed. Applicant's argument regarding a probe array of $4(2^r-1)$ probes has been considered but is deemed moot in view of the fact that the argument does not address limitations of the Claim 125.

Applicant further argues that Deugau et al does not disclose an array of probes which contains a double-stranded portion at the 3' terminus and a single-stranded portion at the 5' terminus or a double-stranded portion at one terminus and a single-stranded portion at the opposite terminus because the indexing linkers of Deugau et al "may have single-stranded portions on both ends". The argument has been considered but is not found persuasive because, as Applicant notes, the second end of Deugau's linker has a protruding end of 0 (Column 9, lines 28-42). Additionally, Deugau et al specifically illustrate the claimed probe containing a double-stranded portion at the 3' terminus and a single-stranded portion at the 5' terminus (Fig. 2). Because Deugau et al teach the second end of their linker has 0 nucleotide protrusion and because they clearly illustrate the a double-stranded portion at the 3' terminus and a single-stranded portion at the 5' terminus (Fig. 2), Deugau et al clearly disclose the probes as claimed.

Applicant cites *In re* Arkley, Eardly and Long and *In re* Le Grice to argue that rejections are proper only when a reference clearly and unequivocally discloses the claimed compound or directs those of skill in the art to the compound without any need for picking, choosing and combining various disclosures not directly related to each other by the teaching of the reference and that a Deugau et al does not direct the reader to select from among the class disclosed only the claimed probes and therefore does not anticipate Claim 70. The arguments

have been considered but are not found persuasive because as stated above, Deugau et al teach the second end of their linker has 0 nucleotide protrusion and they clearly illustrate the a double-stranded portion at the 3' terminus and a single-stranded portion at the 5' terminus (Fig. 2), Deugau et al unequivocally disclose the probes as claimed. Therefore, those of skill in the art would not be required to pick and choose various unrelated disclosures.

Regarding Claim 74, Applicant argues that Deugau et al does not disclose attaching the array of probes to a solid support by conjugating to a coupling agent but instead uses the method of Ghosh et al wherein derivatized solid supports directly link oligonucleotides to the solid support. The argument has been considered but is deemed moot in view of the fact that the argument addresses Claim 74 as amended and in view of the fact that the previous rejection of Claim 74 under 35 U.S.C. 102 is withdrawn.

Regarding Claim 124 (119), Applicant argues that Deugau et al does not disclose an array containing up to $4(2^r-1)$ probes but in stead teach a lower limit for the number of required probes i.e. is $[N \times (N + 1)]/2$. The argument has been considered but is not found persuasive because as stated above, Deugau et al clearly discloses an array comprising **up to** $4(2^r-1)$ nucleic acid probes (Column 9, lines 29-42 and Claim 25). Deugau et al disclose the array comprises at least two probes (Column 9, lines 29-31) and they claim the array comprises at least eight different probes (Claim 25 (ii)). As such, Deugau et al disclose the array comprising "up to $4(2^r-1)$ nucleic acid probes" as claimed. Applicant further argues that Deugau et al does not disclose a degenerative array of probes. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., degenerative array of probes) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. Claim 74-79, 92-94 and 124 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deugau et al (U.S. Patent No. 5,508,169, filed 6 April 1990) in view of Ghosh et al (Nucleic Acids Research, 1987, 15: 5353-5372).

Regarding Claim 74, Deugau et al teach an array of nucleic acid probes wherein each probe comprises a single-stranded portion at one terminus and a double-stranded portion at the opposite terminus wherein the single-stranded portion includes a random nucleotide sequence of length R and one strand of the double-stranded portion is conjugated to a solid support using the method of Ghosh et al (Column 10, lines 45-51, Fig. 2 and Claim 26) but Deugau et al do not specifically teach the probe is conjugated to a coupling agent through which the probes are bound to the solid support. However, Ghosh et al teach the method of binding probes to a solid support wherein the probe is conjugated to a coupling agent (i.e. aminohexyl and cystaminyl functional groups) through which the probes are bound to the solid support (page 5358, second full paragraph). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the coupling agent for probe attachments taught by Ghosh et al to the probe attachments of Deugau et al based on the teaching of Deugau et al wherein their probes are attached using the methods of Ghosh et al

for the obvious benefits of utilizing a preferred and successful method of probe attachment as taught by Deugau et al (Column 10, lines 45-51).

Regarding Claim 75, Deugau et al teach an array of nucleic acid probes wherein each probe has a double-stranded portion and a single stranded portion and a random nucleotide sequence of length R within the single-stranded portion (Column 9, lines 29-42 and Claim 33) wherein the probes are fixed to a solid support as taught by Ghosh et al (Column 10, lines 45-51 and Claim 26) but they do not specifically teach the material from which the solid support is made. However, Ghosh et al teach their solid support is selected from plastics and resins (page 5356, first full paragraph-page 5357, last paragraph). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the solid supports of Ghosh et al to the immobilization of Deugau et al and to immobilize the probes onto plastic or resin support based on the suggestion of Deugau et al (Column 10, lines 45-51 and Claim 26) thereby utilizing well known supports for the expected benefits of successful immobilization.

Regarding Claim 76, Deugau et al teach the array wherein the solid support is a two-dimensional matrix with multiple probe binding sites i.e. the probes are attached to spatially segregated solid phase substrates (Column 10, lines 45-51).

Regarding Claim 77, Deugau et al teach the array wherein the probes are labeled with a detectable label (Claim 27).

Regarding Claim 78, Deugau et al teach the array wherein the label comprises a radioisotope or fluorescent chemical (Claims 27 & 28).

Regarding Claim 79, Deugau et al teach the array wherein the nucleic acids are DNA (Claims 25 and 33).

Regarding Claim 92, Deugau et al teach the array wherein the probes are labeled with a detectable label (Claim 27).

Regarding Claim 93, Deugau et al teach the array wherein the label comprises a radioisotope or fluorescent chemical (Claims 27 & 28).

Regarding Claim 94, Deugau et al teach the array wherein the nucleic acids are DNA (Claims 25 and 33).

Regarding Claim 124, Deugau et al teach the array comprising about 4^r different nucleic acid probes (i.e. complete panel of indexing linkers) (Column 11,lines 14-25).

Response to Arguments

15. Applicant argues that Deugau et al does not disclose attaching the array of probes to a solid support by conjugating to a coupling agent but instead uses the method of Ghosh et al wherein derivatized solid supports directly link oligonucleotides to the solid support. The argument has been considered but is not found persuasive because contrary to Applicant's assertion that Ghosh et al directly link oligonucleotides to the solid support, the probe of Ghosh et al is conjugated to a coupling agent (i.e. aminohexyl and cystaminyl functional groups) through which the probes are bound to the solid support (page 5358, second full paragraph). As such, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the coupling agent for probe attachments taught by Ghosh et al to the probe attachments of Deugau et al based on the teaching of Deugau et al wherein their probes are attached using the methods of Ghosh et al for the obvious benefits of utilizing the preferred and successful method of probe attachment as taught by Deugau et al (Column 10, lines 45-51).

Regarding Claim 75, Applicant argues that because Claim 75 depends from Claim 74 which requires linkage of double-stranded oligonucleotides to the solid support via coupling agents and because Ghosh et al (as cited by Deugau et al) does not attaching via a coupling agent, the cited references individually or in combination do not teach the claimed probe array.

The argument has been considered but is not found persuasive for the reasons stated immediately above i.e. the probe of Ghosh et al is conjugated to a coupling agent (i.e. aminohexyl and cystaminyl functional groups) through which the probes are bound to the solid support (page 5358, second full paragraph). As such, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the coupling agent for probe attachments taught by Ghosh et al to thereby couple the probes of Deugau et al via coupling agent of Ghosh et al.

16. Claims 123 and 126 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deugau et al (U.S. Patent No. 5,508,169, filed 6 April 1990) and Ghosh et al (Nucleic Acids Research, 1987, 15: 5353-5372) as applied to Claim 74 above and further in view of Brenner et al (Proc. Natl. Acad. Sci. USA, 1989, 86: 8902-8906).

Regarding Claim 123, Deugau et al teach an array of nucleic acid probes wherein each probe comprises a single-stranded portion at one terminus and a double-stranded portion at the opposite terminus wherein the single-stranded portion includes a random nucleotide sequence of length R and one strand of the double-stranded portion is conjugated to a solid support using the method of Ghosh et al (Column 10, lines 45-51, Fig. 2 and Claim 26) and Ghosh et al teach the method of binding probes to a solid support wherein the probe is conjugated to a coupling agent (i.e. aminohexyl and cystaminyl functional groups) through which the probes are bound to the solid support (page 5358, second full paragraph). Deugau et al and Ghosh et al do not teach a coupling agent selected from the group consisting of antibody/antigen, biotin/streptavidin, *Staphylococcus aureus* protein A/IgG antibody F_c fragment, nucleic acid/nucleic acid binding protein, and streptavidin/protein A chimeras.

However, biotin/streptavidin coupling agents were well known in the art at the time the claimed invention was made as taught by Brenner et al who teach biotin/streptavidin is a preferred coupling agent wherein the biotin coupling agent can be attached to either the 3' or 5' end and facilitates enhancement of sequence fingerprinting via selective immobilization (page 8904, second full paragraph). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the biotin/streptavidin coupling agent of Brenner et al to the Deugau et al array of probes to thereby selectively immobilize probes for fingerprinting as taught by Brenner (page 8904, second full paragraph) for the obvious benefits of providing an array of selectively immobilized probe e.g. providing means for selective hybridization.

Regarding Claim 126, the claim is drawn to the array of Claim 74 wherein the random sequence of length R in the single-stranded portion in 50% or more of the probes is replaced with a sequence of length R+L having a blocked 3' nucleotide and representing those nucleotide sequences of length R+L in the target nucleic acid sample. The recitation "by extending the single-stranded portion of the probes by ligation of a 3' blocked nucleotide length L using hybridized target as template whereby the random nucleotide sequence of length R is extended" is functional language which does not describe structural components of the claimed array.

"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) see MPEP 2113.

Deugau et al teach an array of nucleic acid probes wherein each probe comprises a single-stranded portion at one terminus and a double-stranded portion at the opposite terminus wherein the single-stranded portion includes a random nucleotide sequence of length

R and one strand of the double-stranded portion is conjugated to a solid support using the method of Ghosh et al (Column 10, lines 45-51, Fig. 2 and Claim 26) but they do not teach the array wherein the random sequence R is replaced by a sequence R+L representing sequences of a target nucleic acid. However, random sequence of R+L was well known in the art at the time the claimed invention was made as taught by Brenner et al who teach a similar array of probes wherein the random sequence of length R in the single-stranded portion of the probes is replaced with a sequence of length R+L having a blocked 3' nucleotide and representing those nucleotide sequences of length R+L in the target nucleic acid sample wherein the extended length R+L provides sequence fingerprints (page 8904, left column, last paragraph and Fig. 4) and wherein the 3' blocked nucleotide provides reliable and efficient sequence comparisons thereby "dramatically" increasing the information content of the fingerprint (Abstract).
It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the extended random sequence R+L of Brenner et al to the at least 50% of the random sequences of Deugau et al to thereby means for fingerprinting and for the expected benefit of "dramatically" increasing the information content of the fingerprint as taught by Brenner et al (Abstract).

Double Patenting

17. The previous rejection of Claims 74-76, 89-94 and 116 under the judicially created doctrine of obviousness-type double patenting over claims 1-18 of U.S. Patent No. 5,631,134 is withdrawn in view of Applicants comments.

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

19. No claim is allowed.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:30 TO 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

BJ Forman, Ph.D.
Patent Examiner
Art Unit: 1634
January 15, 2003